Remarks

Favorable reconsideration of this application and its claims is respectfully requested in view of the above amendments and following remarks. Claims 1-10 have been examined, and claim 11 is considered withdrawn as being directed to a non-elected species. Claims 1 and 8 are amended and supported for instance at page 7, lines 2-3 and in Examples 2 and 3. Claims 5 and 11 have been canceled without prejudice or disclaimer. No new matter has been added. Claims 1-4 and 6-10 are pending.

Translation of Documents

Applicants respectfully clarify that the priority document is the same exact disclosure as the PCT application, and that the translation of one is the translation of the other. Should any further clarification be needed, the Examiner is invited to contact Applicants' representative.

Election/Restriction

Applicants acknowledge their election in the reply of March 4, 2008, and that claim 11 is considered withdrawn as being directed to a non-elected species. Claim 11 has been canceled without prejudice or disclaimer.

Sequence Compliance

Regarding the issues raised in the STIC report, Applicants respectfully submit herewith this response a corrected sequence listing that is in compliance with the rules. Both a computer readable form (CRF) and a paper copy have been submitted, along with a copy of the STIC report.

Claim Rejections- 35 U.S.C. 112

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claim 5 has been canceled rendering the rejection moot. Applicants have canceled claim 5 to expedite prosecution and do not necessarily concede the correctness of the rejection. Nonetheless, Applicants respectfully request that the rejection be withdrawn since claim 5 has been canceled.

Claim Rejections- 35 U.S.C. 103

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jefferies (US 5948426) in view of Rodan et al. (US 5461034). Applicants respectfully traverse the rejection to the extent it is maintained.

Claim 1 is directed to a pharmaceutical composition comprising a safe and efficient amount of osteogenic growth peptide or OGP, a safe and efficient amount of granulocyte colony-stimulating factor or G-CSF and a pharmaceutically acceptable carrier, wherein the molar ratio of OGP to G-CSF is from 0.25:1 to 20:1. Claim 8 is directed to a method of preparing the pharmaceutical composition of claim 1 and having the same molar ratio range of OGP and G-CSF.

Turning to the references cited, Jefferies and Rodan et al. do not render the claims obvious. Both Jefferies and Rodan et al. are directed to bone marrow reconstruction. Jefferies further discusses using various growth factors and their combinations (including growth factors as G-CSF and OGP), and Rodan et al. further discusses use of the particular OGP, ALKRQGRTLYGFGG. However, Jefferies and Rodan et al. do not teach or suggest a pharmaceutical composition as recited in claims 1 and 8. Namely, Jefferies and Rodan et al. clearly do not teach or suggest a pharmaceutical composition where OGP and G-CSF are combined at a molar ratio ranging from 0.25:1 to 20:1 (OGP:G-CSF). In fact, nothing in Jefferies and Rodan et al. suggests specifically combining OGP and G-CSF, much less the combination in the range of molar ratios as claimed. While Jefferies generally discusses various growth factors and mentions that they may be combined and while Rodan et al. discusses use of the particular OGP above, there is no teaching or suggestion to specifically select OGP and G-CSF in the range of molar ratios claimed.

Further, the claims at least provide synergistic effects on blood cell formation (e.g. haematogenesis) that are neither suggested nor recognized by the references cited. In fact, Jefferies and Rodan et al. are directed to bone marrow reconstruction and not blood cell formation. Contrary to the references cited, Applicants' original disclosure demonstrates clear evidence that the claimed invention can provide excellent synergistic effects on haematogenesis. For instance, Example 2 shows that synergistic effects on

blood cell formation were observed when OGP and G-CSF were administered simultaneously (see e.g. "2.5 Discussion" at pages 13-15 and Figs. 1 and 2).

As shown in Fig. 1, it is observed that after day eleven, the count of peripheral blood leucocytes (WBC) in the group co-administered with OGP and G-CSF (e.g. sOGP and rhG-CSF) was significantly higher than those groups administered with either OGP or G-CSF alone. More particularly, Fig. 1 clearly shows that synergistic effects on WBC formation are achieved when OGP and G-CSF are co-administered. For example, day twelve shows that WBC numbers in the group co-administered with OGP and G-CSF was about 40 and almost 100% greater than the sum of WBC numbers in the group administered OGP alone (about 7 and decreasing) and the group administered G-CSF alone (about 16), which is about 23.

Furthermore, Fig. 2 also shows that after day eleven and thirteen, the count of peripheral blood lymphocytes (LY) in the group co-administered with OGP and G-CSF was significantly higher than those groups administered with either OGP or G-CSF alone. More particularly, Fig. 2 clearly shows that synergistic effects on LY formation are achieved when OGP and G-CSF are co-administered. For example, day twelve shows that LY numbers in the group co-administered with OGP and G-CSF was about 11.5 and significantly greater than the sum of LY numbers in the group administered OGP alone (about 4.5 and decreasing) and the group administered G-CSF alone (about 4.5), which is about 9. The synergistic effects on LY formation are even more significant as observed on day fourteen. Example 3 also reports that synergistic effects are observed when changing the molar ratios of OGP and G-CSF and while carrying out the same studies as described in Example 2.

Based on the showing above, Applicants' disclosure is clearly evident that excellent synergistic effects can be obtained by combining OGP and G-CSF at the claimed molar ratio range.

As discussed, Jefferies and Rodan et al. teach or suggest neither the particular combination of OGP and G-CSF, nor the particular range of molar ratios as in claims 1 and 8. The references cited also do not suggest or recognize such excellent results that the claimed invention may have on blood cell formation. Thus, one of skill in the art would not arrive at the invention as claimed based on Jefferies and Rodan et al. The fact

that Jefferies and Rodan et al. are directed to bone marrow reconstruction and not blood cell formation (e.g. haematogenesis), renders these reference even further removed from the claimed invention. For at least the foregoing reasons, claims 1-4 and 6-10 are non-obvious and are patentable.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above amendments and remarks, Applicants respectfully request favorable action in this application in the form of a Notice of Allowance. If any questions arise regarding this communication, the Examiner is invited to contact Applicants' representative at the number listed below.

Respectfully submitted,

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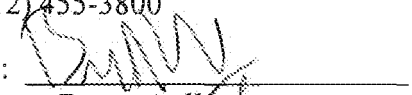
By: 

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